AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 - EXPEDITED PROCEDURE

Serial Number: 09/400365

Filing Date: September 20, 1999

Title: PATIENT SPECIFIC CIRCULATION MODEL

Page 9 Dkt: 1566.002US1

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on October 28, 2003, and the references cited therewith.

Claims 1, 8, 12, 19, 23, and 24 are amended; as a result, claims 1-28 and 52-55 remain pending in this application.

In the Drawings

A proposed new Fig. 30 is enclosed herewith.

The Examiner has objected to the drawings under 37 CFR 1.83(a). Applicant has submitted herewith a proposed new Fig. 30 illustrating the steps of correcting a flow resistance based upon a ratio of a measured flow and a calculated flow. A corresponding amendment of the specification has also been submitted. It is believed that the new drawing overcomes the objection.

Objection to the Declaration

The Examiner has objected to the Declaration as not being in compliance with 37 CFR 1.66 or 1.68. A copy of a new Declaration executed by Lewis Sadler is submitted herewith to overcome the objection

§112 Rejection of the Claims

Claims 12-28, 54, and 55 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claims 12 and 23 herein in a manner consistent with the specific suggestions contained in the office action in order to overcome the rejections of those claims and the claims depending therefrom. The specific rejections of claims 10 and 21 on the basis of indefiniteness, however, are traversed. Claims 10 and 21 recite that the simulation or model is forced with a flow measurement obtained from the living subject. The office action states that it is vague and indefinite as to what the purpose of the simulation and development of a model

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/400365

Filing Date: September 20, 1999

Title: PATIENT SPECIFIC CIRCULATION MODEL

Page 10 Dkt: 1566.002US1

would be if the simulation is going to be forced to use the measured flow anyway. As disclosed in the specification, a forcing function may be, for example, a nominal function or an actual measurement from the patient that is applied to a specific location (e.g., at the root of the aorta) in the model. In the latter case, one of the purposes of the model is to calculate flows and/or pressures at locations within the vascular system other than where the forcing function is applied. Reconsideration and withdrawal of the rejections of claims 10 and 21 are respectfully requested.

§102 and §103 Rejections of the Claims

Claims 1-4, 10-14, 20, and 22-24 have been rejected under 35 U.S.C. 102(b) as being anticipated by Charbel et al. Claims 5-7, and 25-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. in view of either Karplus or Foutrakis. Claims 15-18, 52, and 55 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. in view of the Charbel et al. 1997 presentation abstract. Claims 53 and 54 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. in view of either Karplus or Ortega.

Applicant expressly reserves the right to file one or more continuation applications claiming the same or similar subject matter as the claims rejected by the office action. The rejections of the pending claims before this amendment under sections 102 or 103 are traversed for the record, as all of the prior art rejections are based upon what applicant believes to be an incorrect interpretation of the Charbel 1996 presentation abstract. In arguing that claims 1-4, 10-14, 20, and 22-24 are anticipated by Charbel et al., the examiner states that the validation of the computer model described in the Charbel 1996 presentation abstract includes a "remodeling procedure" to correct for any discrepancies observed between the predicted and actual flow values, citing p. 113, col. 2, lines 11-15 of the abstract. Correction of the computer model, however, is not what is referred to in that document by a "remodeling procedure." The abstract is describing that, in a particular series of patients, a linear correlation was found between predicted and intraoperatively measured blood flow values, both at baseline and after performance of the vascular remodeling procedures. A vascular remodeling procedure in this context is a term of art which refers to a surgical operation that alters the anatomy of part of the circulatory system.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/400365

Filing Date: September 20, 1999

Title: PATIENT SPECIFIC CIRCULATION MODEL

Page 11 Dkt: 1566.002US1

Statement Regarding U.S. Patent No. 6,117,087

In a previous office action, the Kamm reference (U.S. Patent No. 6,117,087) was properly withdrawn as a prior art reference in view of the effective filing date of the then pending claims of February 3, 1998. Applicant neither admits nor denies the prior art status of the Kamm reference, but hereby withdraws the claim to priority based upon the February 3, 1998 filing date for the presently pending claims as amended. Applicant finds no teaching or suggestion in Kamm for adjusting a flow resistance of a circulatory system model based upon a ratio of a measured and a calculated flow as recited by the present claims.

Applicant expressly reserves the right to reassert the claim for priority based upon the February 3, 1998 filing date in this or a later-filed application.

Allowable Subject Matter

Claims 8, 9, and 19 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims as the prior art of record fails to teach adjusting, or a means for adjusting, a flow resistance of the simulation or model of the circulatory system based upon a ratio of a measured and a calculated flow.

Accordingly, applicant has requested herein the amendment of independent claims 1 and 12 to incorporate a recitation to that effect so that claims 1 and 12 would then constitute claims 8 and 19, respectively, in independent form. Applicant has similarly requested amendment of claim 23 to incorporate the same limitation. The recitations of dependent claims 2-11, 13-22, 24-28, and 52-55 are further limitations to the patentable subject matter recited by either claim 1, 12, or 23 and are neither taught nor suggested by the prior art of record in that context. Applicant therefore believes all of the pending claims would be allowable over the prior art of record were the requested amendments to be entered.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/400365

Filing Date: September 20, 1999

e: PATIENT SPECIFIC CIRCULATION MODEL

Page 12 Dkt: 1566.002US1

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

FADY T. CHARBEL ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(847) 432-7302

Date 3-78-03

y <u>x</u>

Reg. No. 33,024

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Box RCE, Commissioner of Patents, Washington, D.C. 20231, on this 2 day of March, 2003

Gina M. Uphus

Name

Signature